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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,778	12/17/2004	Paul John Beswick	PG4814USW	4905

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/518,778	Applicant(s) BESWICK ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 18 is/are pending in the application.
4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 11, 12 and 15 is/are rejected.
- 7) ☐ Claim(s) 4, 7-10 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/17/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to the compound of formula I.

Group II, claim(s) 18-19, drawn to the method of treating various diseases with the compound of formula I

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I and II are linked by the technical feature of the compound of formula I. However, as evidenced by Kamiya et. al., the compound of formula I does not make a contribution over the prior art and does not link the product and method claims into a single general inventive concept. Additionally, alternative members of the Markush group of compounds in Groups I and II do not have a common cores. (See MPEP 1850, Section III, part B.) If applicants elect the product and if it is found free of the prior art, the method claims may be eligible for rejoinder practice under 821.04 (b).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

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must also identify the claims readable on the elected species, including any claims subsequently added.

During a telephone conversation with Robert Brink on 2/15/06 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15 and the species of example 25 on page 75 of the specification was elected. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 12, lines 1-2, page 3, the phrase "wherein phenyl"..." is in the meta position to the depicted N." is unclear. It is not clear which phenyl is being talked about and how it can be in the meta position, since there is more than one phenyl ring in the compound, and more than one phenyl ring that can be bonded to N.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1, 2, 3, 5, 6, 11, 12, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamiya et. al. (See Reference A). Kamiya et. al. discloses the instant compounds 1-2 at column 36, lines 29-33.

Claim(s) 1, 2, 5, 6, 11, 12, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by 68:49243, Hcaplus. (See Reference U). Hcaplus discloses the instant compound RN 17074-85-0.

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Claim(s) 1, 2, 3, 5, 6, 11, 12, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hcaplus 86:55153. (See Reference V). Hcaplus 86:55153 discloses the instant compounds 58336-67-7 and 58336-68-8.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 5, 6, 11, 12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et. al. (See Reference A).

Kamiya et. al. teaches the instant compound as shown in column 37, where R1 is aryl, R2 is lower alkyl, or ar (lower) alkyl, R3 is lower alkyl, R5 is carboxy, R6 is hydrogen, A is lower alkylene, halogen, lower alkoxy. At column 37, lines 1-25, see the compound in claim 37. The difference between the prior art compound and the instantly claimed compounds is the teaching of a genus that overlaps in subject matter with the instant genus of compounds. The patentee teaches a very limited number of selections for the variables of this genus that are small enough in number to be combined to form the instant genus. Since the patentee teaches a small group of compounds within a genus that overlaps in subject matter with the instant genus, it would have been obvious for one of ordinary skill in the art to easily envision and test the compounds that overlap with the prior art genus of compounds. Accordingly, the compounds are deemed

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unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

Claims 1, 2, 3, 5, 6, 11, 12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hcaplus 86: 55153. (See Reference V).

Hcaplus 86: 55153 teaches the instant compound of formula I wherein R is alkyl, R2 and R3 is H, alkyl, R4 is CO2H, Z is alkylene, R1 is alkyl, aryl, aralkyl. The difference between the prior art compound and the instantly claimed compounds is the teaching of a genus that overlaps in subject matter with the instant genus of compounds. The patentee teaches a very limited number of selections for the variables of this genus that are small enough in number to be combined to form the instant genus. Since the patentee teaches a small group of compounds within a genus that overlaps in subject matter with the instant genus, it would have been obvious for one of ordinary skill in the art to easily envision and test the compounds that overlap with the prior art genus of compounds. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

Claims 4, 7-10, 13 are objected to because they are based on rejected claims.

The elected species is allowable.

The IDS filed 12/17/04 has been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0699.

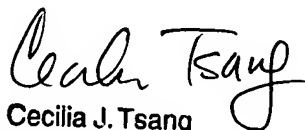
A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



BMR

February 17, 2006



Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600